## REMARKS

Claims 1 and 82 have been amended for clarity as discussed in more detail below. The amendment should not be construed as acquiescence in any ground of rejection. Applicant responds to the Examiner's comments using the paragraph numbering of the office action.

¶2. The Examiner alleges that the present office action is in response to applicant request to remove the finality of the previous rejection. In fact, no such request was made. Rather applicant appealed the final rejection to the Board. The present office action thus represents the Examiner's decision to reopen prosecution rather than respond to the appeal brief.

¶6. Claim 1 has been amended to deleted the redundant recitation of "or."

¶7. Claims 1-2, 4, 6-8, 10-12, 17, 21,-24, 31-32, 35-37, 82-90 and 93-102 stand rejected based on the allegation that it is unclear whether the recitation of human IgG1 isotype applies to all antibodies encompassed by the claim or just the human antibody. Applicant submits it was abundantly clear that the recital that the antibody is of human IgG1 isotype applies to the antecedent recitation of the antibody, which includes all antibodies included in the claim. Nevertheless, to avoid further debate regarding an issue not affecting the merits, applicant has moved the recitation of a human IgG1 isotype to occur before the phrase defining the various types of antibody encompassed by the claim.

¶8. Claims 1-2, 4-6, 10-12, 17, 21-24, 31-32, 35-37, 82-90 and 93-102 stand rejected on the basis that the methods lack enablement for curing Alzheimer's disease or complete prevention of the disease.

Applicant respectfully submits that the imposition of a requirement of completely curing or completely eradicating a disease reflects an unduly high standard of enablement. Treatment of a disease includes but does not require completely curing a disease. Similarly, delaying or reducing risk of onset of a disease includes but does not require completely preventing a disease (*see*, *e.g.*, specification at p. 27, lines 12-20). As properly construed, Appellant respectfully submits that the claims are enabled.

Enabling the full scope of a claim does not necessarily require enabling every embodiment within the claim. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984). This principle is applied to a method of treatment by *In re Cortright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999). One of the claims at issue in *In re Cortright* was directed to a method of treating baldness. The Board had rejected the claim for lack of enablement on the basis that the specification did not show restoring the user's hair to its original state (*i.e.*, a full head of hair) but only some improved growth characterized as "filling-in some" or "fuzz" (*Id.* at 1358, 49 USPQ2d at 1467). The Federal Circuit construed the claims as meaning that the claimed method increased the amount of hair grown on the scalp but did not necessarily produce a full head of hair (*Id.* at 1359, USPQ2d at 1468). The Federal Circuit concluded that the claims, so construed, were enabled, notwithstanding the lack of evidence that complete restoration could be achieved.

The same principle is illustrated in a different technology by *CFMT, Inc. v. Yieldup Int'l Corp*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003). The patent at issue was directed to a method of cleaning semi-conductor wafers. The available evidence showed that the disclosed method could remove some contaminants, but could not remove all contaminants, nor even achieve removal of contaminants to a commercial standard. The Federal Circuit reversed the district court's holding of lack of enablement.

In essence the district court set the enablement bar too high. Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected commercially viable embodiment absent a claim limitation to that effect.

In sum, any meaningful "cleaning" would satisfy the claimed goal of "cleaning of semiconductor wafers." *Id.* at . 1338-1340, 68 USPQ2d at 1944-45.

A recent unpublished decision of the USPTO Board of Patent Appeals and Interferences is instructive in applying the above Federal Circuit precedents to claims encompassing methods of treatment. *Ex parte Saito*, Appeal No. 2005-1442 (BPAI 2005, nonprecedential opinion) concerned claims directed to methods of introducing a nucleic acid into a subject by transplanting a hair follicle modified to contain the nucleic acid. The claims were rejected by the Examiner for lack of enablement because, although the claims were not limited to therapeutic methods, the claims encompassed such methods, and the Examiner took the view that

undue experimentation would be required to achieve therapeutic levels of gene expression. The Board followed the precedent of *In re Cortright* in reversing the Examiner.

As with the present claims, the claims in *Cortright* encompassed a method of obtaining results that might be difficult to achieve: here, therapeutically effective gene therapy; in *Cortright*, complete restoration of hair growth. However, as in *Cortright*, the present claims do not require that particular result: the present claims require only introducing or delivering a nucleic acid; *Cortright's* claims required only some restoration of hair growth.

The court in *Cortright* did not dispute the board's conclusion that completely restoring hair growth using Bag Balm® would require undue experimentation [citation omitted]. The court nonetheless concluded that the claimed method was not nonenabled merely because it encompassed one difficult-to-achieve outcome. The same reasoning applies here: the examiner may be correct that achieving clinically useful gene therapy using the claimed method would require undue experimentation, but the claims are not nonenabled merely for encompassing that difficult-to-achieve outcome. *Ex parte Saito*, *id.* at pp. 6-7.

Here, as in *In re Cortright* or *Ex Parte Saito*, the present claims include but do not require a complete cure or complete prevention. Assuming arguendo that the claimed methods cannot completely cure or prevent Alzheimer's disease, they would be no different than treatment or prophylaxis with many other highly successful drugs. For example, it is well known that the commercial success of certain cancer drugs is measured in increments of extending the life of a patient by few months, a result far removed from complete cure or prevention. Further, a quick search of the PTO database reveals that the Patent Office has granted thousands of patents to methods of treatment and/or prophylaxis of disease notwithstanding that it is common knowledge that few drugs achieve such lofty goals as complete cure or complete prevention. In these circumstances, Appellant submits that in the presently claimed methods, as in other patents claiming methods of treatment or prophylaxis, the possibility that the methods may not achieve a complete cure or complete prevention is not detrimental to enablement and need not be excluded from the claims.

The Examiner also alleges that it would have been impossible to determine whether a method of prophylaxis can be successful. In fact, success of prophylaxis can be determined by experiments in an animal model by treating mice with antibody before development of plaques and detecting a statistically significant reduction between plaques in

treated mice and controls. Prophylaxis can also be determined in a human clinical trial as described at p. 80, lines 7-21. Successful practice of a method of prophylaxis does not require that every patient administered the regime would develop the disease but for the regime, or that the regime completely eliminates all risk of the disease in every patient treated.

¶¶9-21. All art based rejections are based on what in applicant's view is a misinterpretation of the claims, namely, that the recitation of a human IgG1 isotype applies only to the human antibody. In any event, such rejections are moot in view of the amendment described, and applicants do not therefore address the Examiner's remaining comments. Lack of comments should not be construed as agreement with any of the Examiner's comments.

Further, applicants note that claims 10 and 88 were directed to human antibodies, and even under the Examiner' interpretation of the claims were directed to antibodies of human IgG1 isotype. Thus, any allegation in the next office action that rejection of these claims was necessitated by applicant's amendment would be incorrect.

¶¶22-24. If the present claims are allowed in their current form, applicant is prepared to file a terminal disclaimer with respect to US 6,743,427, US 6,761,888 and US 6,913,745. Provision of a terminal disclaimer should not be construed as acquiescence in the merits of the rejection.

¶¶25-32. If the present claims are allowed in their current form, and the claims of US Application Nos. 10/828,548, 10/232,030, 10/923,469, 10/890,071, and 10/923,267 are allowed in their current form, applicant is prepared to file a terminal disclaimer with respect to each of the aforementioned applications. Provision of a terminal disclaimer should not be construed as acquiescence in the merits of the rejection.

Applicant notes that US Application Nos. 10/704,070 and 10/703,713 are abandoned. A notice of abandonment was mailed April 3, 2004 for US Application No. 10/704,070. An express abandonment under 37 C.F.R. 1.138 was filed for US Application No. 10/890,070 on March 29, 2007.

Respectfully submitted,

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